

Inventor : DONG, Zheng Xin et al.  
Serial No. : 09/856,676  
Filed : July 16, 2001  
Page : 13

---

**REMARKS**

This amendment is responsive to the instant Office Action mailed September 15, 2005. Original claims 1-12 are under examination in the present action. Claims 10-12 have been withdrawn from further consideration by the Examiner as being directed to unelected subject matter. Claims 1-9 stand rejected. No claim has been allowed.

In response to the instant Office Action, Applicants have amended page 9, lines 3-19. Applicants have not amended, canceled or withdrawn any pending claims. No new claims have been added.

1. Without conceding the appropriateness of the Examiner's comments, Applicants acknowledge the finality of the restriction requirement as set forth on pages and 3 and 4 of the instant Office Action. Applicants further acknowledge the withdrawal of claims 10-12 in compliance with the restriction requirement. Applicants respectfully renew and reassert, as if stated in its entirety herein, the Request for Rejoinder as set forth in the Response to Restriction Requirement submitted June 8, 2005.

2. Applicants are grateful for the entry of the Information Disclosure Statement filed June 8, 2005 and are grateful for the Examiner's consideration of the reference documents cited therein.

3. Claims 1-9 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

Inventor : DONG, Zheng Xin et al.  
Serial No. : 09/856,676  
Filed : July 16, 2001  
Page : 14

---

matter which the Applicants regard as their invention. In support for this rejection, the Examiner argues that the abbreviation, "Hppa", used to denote a synthetic amino acid found in the elected peptide analogue of glucagon-like peptide-1, i.e., hGLP-1(7-36)-NH<sub>2</sub>, is not disclosed and/or defined in the specification. Applicants respectfully disagree with the Examiner's position. As set forth in 37 C.F.R. §1.77(b)(3) and (b)(12), a "Sequence Listing" is considered a necessary part of a specification when required. As noted in entry <210> on page 30 of the paper Sequence Listing accompanying Applicants' Petition to Withdraw Examiner's Holding of Abandonment submitted January 23, 2004, "Hppa" is defined therein under entry <223> as "3-(p-hydroxyphenyl)propionic acid". As such, Applicants distinctly claim an analogue of human glucagon-like peptide-1 (7-36) amide [hGLP-1(7-36)-NH<sub>2</sub>] wherein the histidine residue found in the 7<sup>th</sup> position of native human GLP-1(7-36)-NH<sub>2</sub> has been replaced with the synthetic amino acid 3-(p-hydroxyphenyl)propionic acid.

Without conceding the correctness of the reasoning of the Examiner's rejection, however, the Applicants have amended the description to specifically include "Hppa" in the list of abbreviations for synthetic amino acids used in the claimed substituted analogues as found on page 9 of the international publication of the parent PCT application, i.e., WO 00/34332. Applicants respectfully assert that this

Inventor : DONG, Zheng Xin et al.  
Serial No. : 09/856,676  
Filed : July 16, 2001  
Page : 15

---

aforementioned Sequence Listing was filed in the claimed priority application, i.e. U.S.S.N. 09/206,833 cited by the international application, i.e. PCT/US99/28929, which the instant application is a 371 application thereof, on August 27, 1999 preceding the international filing date of December 7, 1999 and the 371 date of July 16, 2001 of the instant application.

Applicants request reconsideration and withdrawal of the rejection of claims 1-9 under 35 U.S.C. §112, second paragraph.

4. Claims 1-9 stand rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the enablement requirement. In support for this rejection, the Examiner argues that the abbreviation, "Hppa" is not disclosed in the specification. Since they are of the opinion that it is applicable, Applicants respectfully reassert the above-detailed argument in opposition to the §112, second paragraph rejection, as if stated in its entirety herein, against the current rejection. Applicants contend once again that "Hppa" was clearly defined in the specification at the time the instant application was filed, and as such, the specification did in fact contain a written description of the invention in full, clear, concise and exact terms so as to enable one skilled in the art to which it pertains to make and use [Hppa<sup>7</sup>]hGLP-1(7-36)-NH<sub>2</sub>, as originally claimed.

Inventor : DONG, Zheng Xin et al.  
Serial No. : 09/856,676  
Filed : July 16, 2001  
Page : 16

---

Applicants request reconsideration and withdrawal of the rejection of claims 1-9 under 35 U.S.C. §112, second paragraph.

Reconsideration of the instant Office Action, allowance of the pending claims, rejoinder of withdrawn claims 10-12 and allowance of said withdrawn claims are respectfully requested. Prompt and favorable action is solicited.

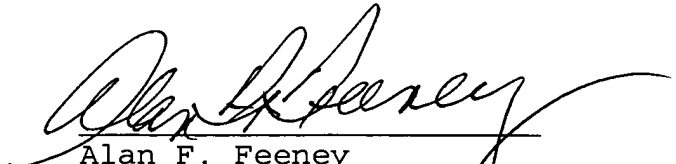
Should Examiner Borin deem that any further action by the Applicants would put this application in order for acceptance, he is invited to telephone Applicant(s) attorney at (508) 478-0144 to facilitate prosecution of this application.

With the exception of the fee for the Petition for a three months extension under 37 C.F.R. §1.136(a), Applicants believe that no fees are due with this response; the Commissioner is, however, hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-0590.

Respectfully submitted,

Date:

3/14/2006

  
Alan F. Feeney  
Attorney for Applicant(s)  
Registration No.: 43,609

IPSEN (Biomeasure)  
27 Maple Street  
Milford, MA 01757-3650  
(508) 478-0144 Telephone  
(508) 478-2530 Facsimile